Applicant: Hugh R. Sharkey et al. Attorney's Docket No.: 14170-043002 / 25-31-0023

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## **REMARKS**

Applicant's representative thanks the Examiner for the courtesy of the telephone interviews conducted September 13 and 14, 2006. During the interview of September 13<sup>th</sup>, agreement was reached that the amendment to the specification identifying applications which are relied upon for continuity is not inaccurate and that the oath or declaration is not defective.

During the interview of September 14<sup>th</sup>, the rejection of claims over Sand in view of Anderson was discussed, no agreement was reached. The substance of the interview is incorporated into the remarks below.

The Examiner has provided the following response to arguments:

Applicant argues that Sand ('709) teaches away from the use of RF energy at column 3, lines 11-22. The examiner respectfully notes that in this passage, Sand ('709) teaches away from the use of RF energy to shrink **corneal** collagen, as clearly set forth in the cited passage, there is no hint that the variation in topography of a few microns – a distance which yields a huge change in refractive performance of the cornea is problematic for vascularized tendons, which are hundreds of microns in diameter. It is also further shown by Anderson et al to be acceptable energy to heat tissue such as tendons.

While, as the Examiner has stated, there is no hint in Sand that a variation in topography of a few microns is problematic for vascularized tendons, more to the point, Sand teaches away from the use of RF energy to shrink tissue and there is no description or suggestion in Sand or Anderson for the use of RF energy to shrink tissue. And, while Anderson describes the use of RF energy to heat tissue such as tendons, such use is to melt tissue not to achieve a controlled modification of a geometry of the tissue.

The Examiner's rejection further states:

Claims 57-66 are rejected under 35 U.S.C. 102(a) as being unpatentable over Sand ('709) in combination with Anderson ('216). Sand ('709) teaches a method such as claimed except the use of RF, use of painting strokes, and use on patellar tendons per se. Anderson ('216) teaches equivalence of RF energy and laser

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energy for heating tissue. It would have been obvious to artisan of ordinary skill to employ RF energy in the method of Sand ('709) since this is not critical and these equivalent for tissue heating, as taught by Anderson ('216) to employ the method on patellar tendons, since Sand ('709) does not discuss avoiding these structures when heating tendons attaching the long bones; to employ a painting motion, since this would allow a substantial length of the tendon to be treated all at once, and to deflect the probe, as taught by Anderson et al, since Sand ('709) teaches no particular technique to reach the internal tissues which are contemplated to be treated, and since this is not critical, thus producing a method such as claimed.

Applicant respectfully disagrees. Sand teaches away from the use of RF energy to shrink tissue – clearly showing that the type of energy employed in the method of Sand is indeed critical. Furthermore, there is no description or suggestion in Anderson that RF and laser energy are equivalent for shrinking tissue. Anderson describes that RF or laser energy can be used to do what Anderson describes doing – melting the free ends of collagen fibrils. While Anderson discusses temperatures at which undesirable thermal shrinkage begins to occur (see, e.g., col. 4, lines 41-44), Anderson does not describe or suggest that RF and laser energy are equivalent to shrink tissue. In fact, according to Sand, RF and laser energy are not equivalent to shrink tissue.

What Sand presents to one skilled in the art is a laser system to irradiate collagen tissue to produce corrective shape changes by controlled and predictable collagen shrinkage (see, e.g., Sand at col. 6, lines 55-61 and col. 8, lines 64-67), and a discussion teaching away from the use of RF energy when treating the cornea stroma (Sand at col. 3, lines 11-22). Clearly there is nothing is Sand that describes or suggests applying RF thermal energy to a ligament, tendon or joint capsular tissue. One skilled in the art thus takes away from Sand that laser energy is a good means for shrinking collagen tissue, and that one should not use RF energy to shrink collagen tissue in the eye. It therefore follows that one means of inducing temperature change is not equivalent to another.

What Anderson presents to one skilled in the art is that since the free ends of Type 1 collagen fibrils melt at a lower temperature than intact collagen fibrils, the free ends can be welded together by melting the free ends at a temperature below the melting temperature of

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intact collagen fibrils (tissue shrinkage temperature) (Anderson at col. 3, lines 55-67), and Anderson describes the use of both laser and RF systems for heating tendon tissue to melt the free ends. Anderson further discusses the temperature at which intact collagen fibrils melt (see, e.g., col. 2, lines 50-55 and col. 9, lines 7-9). One skilled in the art thus takes away from Anderson that the free ends of collagen fibrils can be welded together without shrinking the collagen fibrils and that RF or laser systems can be used to heat the tissue to weld the free ends.

There is no motivation or suggestion in the references for the combination proposed by the Examiner. Sand's description focuses on the desirability of using laser energy. Anderson's description focuses on using an acceptable temperature range to weld tissue that is below the tissue shrinkage temperature. There is nothing in Anderson that describes or suggest that the method of Sand should be carried out with RF energy. Thus, one skilled in the art presented with Sand and Anderson, would not go back to using RF energy in the method of Sand, whether the method of Sand is being used to treat the eye or collagen connective tissue elsewhere in the body. The Examiner is thus relying on impermissible hindsight, using the applicant's claims as a template in combining the references.

The Examiner has rejected claim 67 further in view of Makower. Applicant submits that Makower does not overcome the deficiencies in Sand and Anderson discussed above.

Applicant requests that the double patenting rejections be held in abeyance until the claims are found to be allowable.

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Respectfully submitted,

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